K121303

Canon

JUL 26 2012

5. 510(k) SUMMARY

Submitter:	Canon, Inc. – Medical Equipment Group 30-2 Shimomaruko, 3-chrome Ohta-ku, Tokyo 146-8501 Japan
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Date Prepared:	April 24, 2012 *revised June 27, 2012*
Trade Name:	XEPHILIO MC-1100
Common Name:	Mobile C-Arm
Classification Name:	OWB 892.1650 Solid State X-Ray Imager (Flat Panel/Digital Imager) OXO 892.1650 Mobile Image-Intensified Fluoroscopic X-Ray System

Predicate Devices:

K090590	MQB	Veradius, Philips
K021049	JAA/OXO	OEC 9800 Plus, GE Healthcare
K093688	MQB	URS-50RF, Virtual Imaging (A Canon USA Company)
K111824	MQB	CSX-10, Canon, Inc.

Device Description:

The XEPHILIO MC-1100 mobile fluoroscopy system consists of two mobile units: a Mainframe (C-Arm) and a Workstation. The Mainframe (C-Arm) is comprised of a high voltage generator, x-ray control, and a "C" shaped apparatus, which supports an X-ray tube and a flat panel detector [Canon CSX-10].

The Mainframe is designed to perform linear and rotational motions that allow the user to position the x-ray imaging components at various angles and distances with respect to the patient. The Mainframe can be used to acquire both still and moving images.

The Workstation is a mobile platform that supports image display monitors and image processing. Interfaces are provided for optional peripherals such as recording and printing devices.

Statement of Intended Use:

The XEPHILIO MC-1100 mobile fluoroscopy system is designed to provide fluoroscopic and spot-film radiographic images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

Summary of Technological Characteristics:

Comparisons with the predicate devices show the technological characteristics of the XEPHILIO MC-1100 are substantially equivalent to the predicate devices.

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5. 510(k) SUMMARY (continued)

Summary of Non-Clinical / Test Data:

Tests were performed on the XEPHILIO MC-1100 which demonstrated that the device is safe and effective, performs comparably to the predicate device(s), and is substantially equivalent to the predicate device(s). Tests included verification/validation testing to internal functional specifications (including software) and non-clinical image comparisons involving flat panel display images taken with the new device and the predicate device(s). Documentation was provided demonstrating compliance of the XEPHILIO MC-1100 to all FDA requirements stated in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, including results of verification/validation plus traceability of verification/validation tests to software requirements and software risk hazards.

Testing confirmed that the XEPHILIO MC-1100 complies with the U.S. Performance Standard for radiographic equipment and with relevant voluntary safety standards for Electrical safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1, 60601-1-1, 60601-1-2, 60601-1-3, 60601-1-4, 60601-2-7, 60601-2-28, 60601-2-32, and 60601-2-43.

Together, these verification/validation activities successfully demonstrated that the XEPHILIO MC-1100 correctly performs as designed, has been validated for its intended use, and raises no new questions regarding either safety or effectiveness when compared to the predicate device(s). Therefore, the verification/validation testing conducted supports a determination of substantial equivalence for the XEPHILIO MC-1100 device.

Conclusion:

Canon, Inc. – Medical Equipment Group considers the *Mobile C-Arm XEPHILIO MC-1100* to be substantially equivalent to the predicate devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 26 2012

Canon, Inc. – Medical Equipment Group
% Ms. Diane Rutherford
Regulatory Engineer
Ken Block Consulting
1201 Richardson Drive, Suite 280
RICHARDSON TX 75080

Re: K121303
Trade/Device Name: XEPHILIO MC-1100
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO and OWB
Dated: April 24, 2012
Received: May 1, 2012

Dear Ms. Rutherford:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number:

Device Name: XEPHILIO MC-1100

Indications for Use:

The XEPHILIO MC-1100 mobile fluoroscopy system is designed to provide fluoroscopic and spot-film radiographic images of the patient during diagnostic, surgical and interventional procedures. Examples of clinical application may include cholangiography, endoscopy, urologic, orthopedic, neurologic, vascular, cardiac, critical care and emergency room procedures. The system may be used for other imaging applications at the physician's discretion.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
510K K121303